

NOV - 8 2000

K 002640

**J. MORITA**

**USA INC**

**9 Mason  
Irvine, CA 92618**

**Phone # (800)-831-3222  
Fax # (949)-581-8811**

**510 (K) SUMMARY**

**Submitters Information**

**Name**

**J. Morita USA Inc.**

**Address:**

**9 Mason  
Irvine, CA 92618**

**Phone Number:**

**(800)-831-3222**

**Fax Number:**

**(949) 581-8811**

**Person To Contact:**

**Vic Mazzanti  
Technical Services Mgr.**

**Date Of Summary:**

**August 22, 2000**

**Trade Name of The Device:**

**FREEDOM**

**Common Or Usual Name:**

**film Processor**

**Classification Name:**

**Dental Automatic  
Radiographic film Processo**

**Technical Characteristics of the Device:** The design of the **FREEDOM** processor is based on a patent held by a dentist, Dr. Steve Blume' of Laguna Hills California. The Developer and Fixer are stored in separate reservoirs higher then the Reaction tank (where the developing, fixing and washing occur). The force of gravity fills the reaction tank first with developer for the proper amount of time. Then the tank is rinsed with fresh running water to remove any residual Developer. After the rinse and drain, the fixer is allowed to fill the reaction tank until it is full. After the appropriate amount of time the fixer is returned to the storage tank by vacuum. Rinse water is then allowed to fill the tank for the final wash. After the proper amount of time the water is drained very slowly which allows water to be pulled off the film by surface tension. After the water is completely drained, the drying cycle starts which directs warm air over the film until it's dry. At the end of the drying cycle an audible signal alerts the user that the films have been fully processed.

**Assessment of non-clinical performance:** During the evaluation period film density was measured to a desired standard of 1.5 over base fog. An Schick Discovery x-ray unit operated at 70kv. And 10ma. Was used to expose a film analyzer by Spectronics that equaled the density of a Mandibular second molar. The films were then read using an X-Rite model 331, serial # 038927 B-W transmission Densitometer. The developer time was then adjusted to accommodate several film manufactures sensitivity. The fixer cycle was determined by the clearing time required to clear the emulsion which did not react with the developer. A cushion was then allowed to clear any film the dentist may use. For example, the Agfa film took 10 seconds longer to clear then Kodak film.

The wash cycle length was determined by the retention of Sodium Thiosulfate by the emulsion. A Hypo Retention kit was used to determine the retention of the salts to an acceptable level.

The dry cycle was determined by visual inspection of the film. The film had to be completely dry to the touch.

**Substantial Equivalence Claim:** The J. Morita USA Inc. FREEDOM PROCESSOR is Substantially equivalent to Dental X-ray Support Systems DXXS automatic film processor.

**Description Of The Device:** The J. Morita USA Inc. FREEDOM PROCESSOR is an automatic dental film processor that continuously develops, fixes, and dries all types of dental x-ray film. Intra-oral as well as Extra-oral films. It processes these films with out the use of rollers. The film is stationary and solution is transferred back and forth from storage tanks. This is done by the use of gravity and vacuum.

**Intended Use of the device:** The device is manufactured for the purpose of processing dental x-ray film continuously from dry state to dry state. The unit will produce archival quality film for the operator. With the use of a day light loader (optional) the films may be processed under any type of light.

One of the many advantages of the Freedom Processor is that maintenance is virtually eliminated since the unit does not posses rollers. The user display prompts the operator effortlessly the process.

**Assessment of Non-Clinical Performance:** During the evaluation the FREEDOM Processor produced x-rays of archival quality using accepted film analyzer device and a densitometer. These films were of comparable quality to the Dental X-ray Support Systems DXSS automatic film processor.

**Conclusions of Non-Clinical Performance:** The performance of the J. Morita USA Inc. FREEDOM Processor during the non-clinical evaluation would indicate that the system is substantially equivalent mechanically, electrically, and radiographically to the Dental X-ray Support Systems DXSS automatic film processor.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV - 8 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Victor Mazzanti  
Technical Services Manager  
J. Morita USA, Inc.  
9 Mason  
Irvine, CA 92618

Re: K002640  
"Freedom" Automatic Film Processor  
Dated: October 9, 2000  
Received: October 11, 2000  
Regulatory class: II  
21 CFR 892.1900/Procode: 90 IXW

Dear Mr. Mazzanti:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with ~~the Current Good Manufacturing Practice~~ requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.  
Captain, USPHS  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): \_\_\_\_\_

Device Name: K002640

Indications For Use:

**The J.Morita USA Inc. "FREEDOM" roller-less automatic film processor is designed to Develop, Fix, Wash and dry Dental x-ray film. It will process all Intra-oral size film from # 0 pedo film to # 4 occlusal film. It will also Process extra-oral film from size 5"x12" to 8"x10".**

**The unit may be placed in a traditional darkroom, or with the optional daylight loader placed in a room with natural or artificial light.**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K002640

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_